IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | |
|---|---|
| In Re Application of | ) |
| | ) |
| ATSUSHI YAMAMOTO et al. | ) |
| | ) |
| Filed: November 8, 2000 | ) |
| | ) |
| Serial No.: 09/674,931 | ) |
| | ) |
| For: Toothbrush | ) |

DECLARATION UNDER RULE 1.132

As one of the inventors, I hereby declare that the following described experimentation was carried out as indicated.

Name of the Inventor: Atsushi Yamamoto

Inventor's Signature: _____

Residence: _____

_____

Citizenship: _____

1. Date of experimentation

From November 25 to 26, 2004

2. Place of experimentation

At a Mechanical Laboratory of Product Research and Development Division of SUNSTAR INC. having an address of 3-1, Asahimachi, Takatsuki-shi, Osaka 569-1195 Japan.

3. Experimenter

The experimenter's name is Atsushi YAMAMOTO, who is the first inventor of the present invention and now belongs to the above-mentioned Mechanical Laboratory of Product Research and Development Division. He was born in 1969 and he graduated from Kyoto Institute of Technology. His background is in molding engineering.

He joined Sunstar Inc. (an Assignee of the present patent application) in 1994. Since he has joined the company, he has been continuously taking charge of developing toothbrushes, e.g. "Do Power" (1996), "Ora 2" (1999), "Do Clear W" (1999), "Butler for children" (2002), "Do Standard" (2004), and so on. Good Design Prize has been given to "Ora 2" and "Butler for Children". "Do Clear W" is a product of the present invention.

4. Purpose of experimentation

The purpose of the experimentation was to clarify a difference of brushing effect between toothbrushes of the cited references and those of the present invention.

5. Content of experimentation

a) Method of experimentation

Sample toothbrushes 1 to 5 as described in the following Table 1 were prepared and cleaning performance of each toothbrush was evaluated after brushing a jaw model set on a brushing simulator.

The shape of tufting holes of samples 1 to 4 is circular. But the shape of tufting holes of sample 5 is elliptic, wherein a lengthwise direction of the tufting holes is along the direction of the handle length. The shape of tufting holes of sample 5 is similar to that of the present invention.

The tufting holes of samples 1 and 2 are not inclined. But the tufting holes of samples 3 and 4 are inclined by 6 degrees, in directions perpendicular to lengthwise directions of the handle length, toward a tufting surface so as to have tufts implanted therein support one another.

The end portion of each tuft of samples 1 and 3 is a flat shape and that of samples 2, 4 and 5 is a chisel shape.

(Table 1)

| | Shape of tufting holes | Inclined angle of tufting holes | Shape of end portion of tuft |
|---|---|---|---|
| Toothbrush 1 | Circular | 0° | Flat shape |
| Toothbrush 2 | Circular | 0° | Chisel shape |
| Toothbrush 3 | Circular | 6° | Flat shape |
| Toothbrush 4 | Circular | 6° | Chisel shape |
| Toothbrush 5 | Elliptic | 6° | Chisel shape |

b) Steps of experimentation

Step 1

A toothbrush and a jaw model were set on a brushing simulator. The toothbrush was provided at the neck portion with a warp gage (manufactured by Kyowa Dengyo company, type KFG-2-350-C1-11L1M2R) in order to control a brushing pressure.

Step 2

First, a spray for checking for dental occlusion (brand name "Occlude," Pascal Co., Ltd.) was applied to the jaw model as a sample stain and then the buccal surface of the left side first molar of the jaw model was brushed using the sample toothbrush and a brushing simulator. The brushing conditions are described in the following Table 2.

(Table 2)

| Items | Conditions |
|---|---|
| Way of brushing | Brushing in an almost horizontal direction |
| Evaluated portion | Buccal surface of the upper left first molar |
| Brushing pressure | 100 g |
| Brushing time | 2.5 sec |
| Strokes | 10 mm |
| Back and forth times | 8 times |

Step 3

After brushing under the above-mentioned conditions, the jaw model was changed to a new one without changing the toothbrush.

Step 4

The above-mentioned Steps 1 to 3 were repeated three times each.

Step 5

After all the brushing, the evaluated portion of the jaw model was photographed by using a camera manufactured by Nikon (COOLPIX 4500).

Step 6

The photographed image was analyzed by using "Photo Shop" of Adobe Company and "NIH Image" of US National Institutes of Health so that stain removing rate (cleaning performance) was calculated. The ratio was calculated by the following Formula (1).

Stain removing ratio (%) = [(area of whole teeth) - (area of being stained) / (area of whole teeth)] x 100 ..... Formula (1)

6. Results of experimentation

The stain removing ratio of each sample toothbrush obtained by the above mentioned experimentations are described in the following Table 3. Toothbrush 5 is similar to that of the present invention.

(Table 3)

| | Stain Removing Ratio (%) | | | |
|---|---|---|---|---|
| | 1st time | 2nd time | 3rd time | Average |
| Toothbrush 1 | 79.1 | 83.4 | 82.9 | 81.8 |
| Toothbrush 2 | 83.4 | 80.2 | 63.7 | 75.7 |
| Toothbrush 3 | 77.1 | 89.5 | 86.3 | 84.3 |
| Toothbrush 4 | 90.2 | 80.6 | 88.5 | 86.4 |
| Toothbrush 5 | 91.6 | 90.8 | 85.1 | 89.2 |

7. Evaluation

a) Cleaning performance due to an inclination of tufting holes

This performance was evaluated by comparing the stain removing ratio of each toothbrush having a same shape of end portion of the tuft and a different inclined angle of the tufting holes, i.e. toothbrushes 1 and 3, and toothbrushes 2 and 4.

As shown in the above-mentioned Table 3, the stain removing ratio of toothbrush 1 having no inclined angle of tufting holes is 81.8% in average, but that of toothbrush 3

having an inclined angle of tufting holes is 84.3% in average. This shows that the inclination of tufting holes improves the cleaning performance.

In addition, the stain removing ratio of toothbrush 2 having no inclined angle of tufting holes is 75.7% in average, but that of toothbrush 4 having an inclined angle of tufting holes is 86.4% in average. This shows also that the inclination of tufting holes improves the cleaning performance.

b) Cleaning performance due to an elliptic shape in addition to an inclination of tufting holes

This performance was evaluated by comparing the stain removing ratio of each toothbrush having a same inclined angle of tufting holes and a different shape of tufting holes, i.e. toothbrushes 4 and 5.

As shown in the above mentioned Table 3, the stain removing ratio of toothbrush 4 having a circular shape of tufting holes is 86.4% in average but that of toothbrush 5 having an elliptic shape of tufting holes is 89.2% in average. This shows that the elliptic shape of tufting holes improves the cleaning performance.

Docket No.: 001348

CERTIFICATE OF MAILING

Express Mail Label No EV 363553613 US

I hereby certify that on December 9, 2004, the attached Amendment, Petition for Extension of Time and Declaration under Rule 1.132 was deposited with the United States Postal Service as Express Mail utilizing the Express Mail Post Office to Addressee Service, postage pre-paid, addressed to:

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Barbara A. Konopski
(Signature)

Barbara A. Konopski

December 9, 2004

Reprinted from *The Journal of Clinical Dentistry,* Volume X, Number 4, 1999

# Plaque Removal Efficacy of the V-Shaped Toothbrush With New Designs in Bristle Arrangement

**Takashi Hanioka, DDS, PhD · Muneo Tanaka, DDS, PhD**
**Miki Ojima, DDS Keiko Takaya, DDS**
**Satoshi Shizukuishi, DDS, PhD**

**Department of Preventive Dentistry**
**Osaka University Faculty of Dentistry**
**Osaka, Japan**

## Abstract

Experimental bristle arrangements were applied to a conventional V-shaped bristle-design toothbrush in an effort to improve plaque removal efficacy in interproximal areas. A single-blind cross-over study was performed to evaluate the plaque removal efficacy of this new bristle arrangement by comparing it to either a more conventional V-shaped toothbrush or a flat-headed toothbrush. Plaque removal efficacy was determined by assessing the percentage of plaque score reduction following a single controlled brushing. The new toothbrush bristle arrangement had a significantly higher plaque removal percentage efficacy than both the V-shaped toothbrush (59.1% vs. 48.5%; $p = 0.0092$) and the flat-headed toothbrush (65.3% vs. 55.3%; $p = 0.0260$) in interproximal areas. These differences were also consistent with whole mouth comparisons. When the subjects were asked about their preferences for the three different bristle formats used in this study, there was no significant difference of opinion found. These findings indicated a superiority of the new toothbrush to the other two, more conventional toothbrush bristle styles on plaque removal efficacy with these study subjects, but no particular preference for bristle design. **(J Clin Dent 10:127–130, 1999.)**

## Introduction

Dental plaque is a primary etiological factor for dental caries and periodontal disease.[1] In developed countries, mechanical toothbrushing serves as the most common method used to remove plaque from all tooth surfaces and in the gingival sulcus.[2] As common as the toothbrush is, it is also well documented that toothbrushing is not a perfect mechanism for plaque removal because of variations in design, and the motor skills and motivation of users. Currently, a number of new toothbrush bristle designs have been developed to attempt to remove more plaque than more conventional V-shaped and flat-headed toothbrush configurations.

One of the primary targets for increased efficiency in the development of new toothbrush designs is in interproximal surfaces.[3] While there are existing additional approaches currently available to remove plaque from proximal surfaces, such as a specific interdental toothbrush or dental floss, people seem not inclined to use more than one, or possibly two instruments to remove plaque. This has motivated designers to develop new toothbrushes that could remove more plaque in the interproximal area compared to a traditional toothbrush. This improvement might offer significant improvements in long-range dental care. In laboratory studies, compared to a traditional flat-headed toothbrush, one V-shaped toothbrush was found to improve plaque removal efficacy on proximal surfaces as a further development and improvement of toothbrush design.[4,5]

Recently, other new technologies have been developed in toothbrush engineering. Various marketed designs of bristle arrangement are now available with a different angulation of bristles, compared to traditional bristles being perpendicular to the brush head. There are also various shapes of bristle bundles in the toothbrush, and combinations of both new angles and shapes. The aim of this study was to evaluate the plaque removal efficacy of a V-shaped toothbrush, incorporating new bristle-arrangement designs in the brush head, in a one-time use clinical protocol.

## Materials and Methods

The new toothbrush (Do Clear W™, Sunstar Inc., Osaka, Japan) was compared to two control toothbrushes (Figure 1). The control toothbrushes, both manufactured in Japan, were of a more conventional V-shaped and flat-headed design.

The new toothbrush was developed to improve plaque removal efficacy at the interproximal region of tooth surfaces. Two major modifications in bristle arrangement were considered in the head of the new Do Clear W toothbrush, in addition to a conventional V-shaped design (Figure 2). Figure 3 illustrates

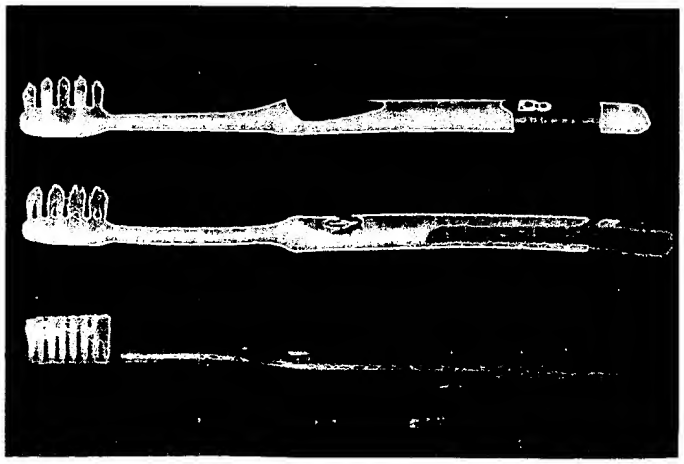

**Figure 1.** *Three test toothbrushes used in the study: New toothbrush, Sunstar Do Clear W (top) and the controls, conventional V-shaped (middle) and flat-headed toothbrush (bottom).*

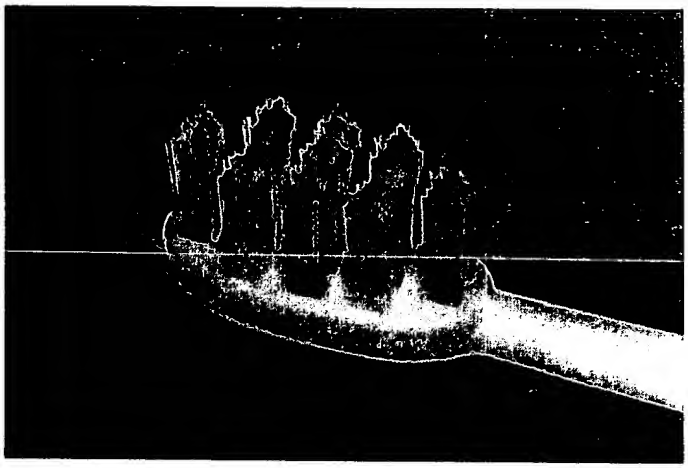

**Figure 2.** *Head of Sunstar Do Clear W toothbrush.*

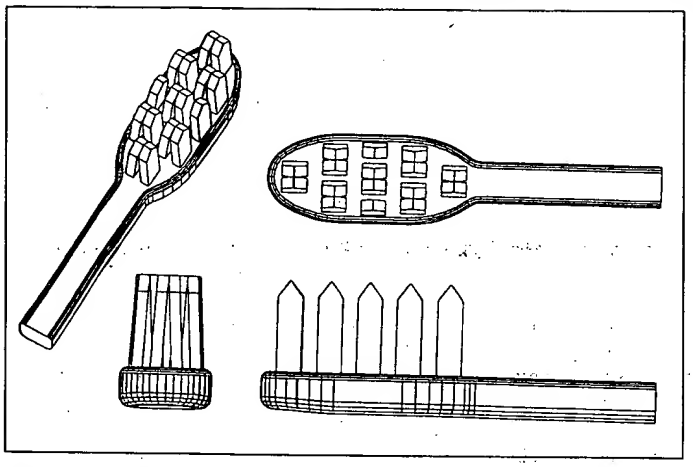

**Figure 3.** *Schematic illustration of bristle arrangement in the new toothbrush, Sunstar Do Clear W.*

this new arrangement of bristle bundles in the new Do Clear W toothbrush. The toothbrush head consists of 16 bristle bundles, 14 of which are paired. The first modification is the rectangular setting of bristle bundles, with the long side parallel to the toothbrush axis. The second modification is the different angle of the paired bundles, which lean against each other at the tip.

A total of 44 medically healthy subjects (16 females and 28 males) between 19 and 22 years of age were recruited from among dental school students. All Ramfjord teeth or substitutions were present without crowns or large restorations. Informed consent was obtained prior to the study.

The format of the study design is presented in Figure 4. At the first visit, plaque scores of pre- and post-brushing with the flat-headed toothbrush were taken. Subjects were then divided into two groups, each consisting of 22 subjects. The groups were balanced based on the plaque removal efficacy total scores after using the flat-headed toothbrush. A single-blind crossover design was employed to compare the plaque removal efficacy of the new Do Clear W toothbrush to either the conventional V-shaped or the flat-headed toothbrush. After the assessment of plaque levels, the experimental teeth were scaled and polished.

One week after the first visit, the teeth of the subjects of each group were polished, and subjects were provided with either the new or conventional toothbrush by random assignment. They

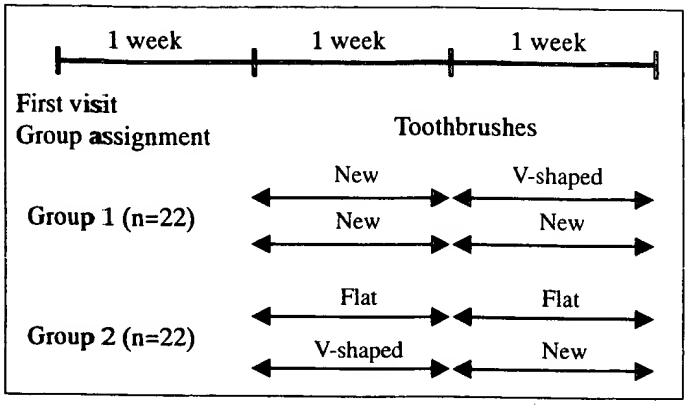


**Figure 4.** *Format of the study design.*

were asked to brush with their assigned toothbrush for 6 days using their normal brushing patterns. All subjects were given the same dentifrice to use during the study. On the seventh day, the subjects reported to the clinic and were given a new toothbrush of the same type that had been assigned during the previous week. Plaque removal efficacy was assessed, as described before. The same procedure with the alternate toothbrush was followed again, with six-day home use, then a seventh-day plaque removal assessment. Following each of the seventh-day assessments, the subjects received a preference questionnaire for the toothbrush just used.

To assess plaque removal efficacy, subjects were asked to refrain from any form of plaque removal or tooth cleaning after dinner, until the examination was performed at around 3:00 PM on the following day. The assessment of plaque removal was performed using the Suzuki method, as described previously.[6,7] Plaque was first disclosed with Red Cote (John O. Butler Co., Chicago, IL). The height of plaque from the gingival margin was measured with a periodontal probe graded to the nearest 0.5mm, placed at mesial and distal line angles and at the midline between the line angles of both facial and lingual aspects. The measurement at line angles was performed carefully to assess the height of plaque as close to the contact as possible. Plaque scores were recorded by three trained and calibrated examiners who were blinded to the toothbrush assignments. Each examiner saw the same subjects throughout the experimental period.

Following the assessment of the amount of plaque accumulated, plaque removal efficacy was determined from the average plaque scores, and the percent of plaque differential in pre- and post-brushing scores compared to the same index score before toothbrushing. The percent plaque removal efficacy was calculated as the: ([pre-brushing plaque score] – [post-brushing plaque score])/(pre-brushing plaque score) ÷ 100. The average plaque removal efficacy for each subject was calculated for line angle plaque scores and whole mouth scores. The differences in the plaque removal efficacy between the toothbrushes were tested using paired t-test. The preference questionnaire was analyzed using a Mann-Whitney test. A minimal significance level was set at $p < 0.05$.

## Results

A total of three subjects, two from the first group and one from the second, were dropped during the study period. The new Do Clear W toothbrush was compared with the conventional

**Table III**
Response of Subjects to the Preference Questionnaires for the Toothbrushes

| Group | Toothbrush | Percent of Preference (N) Favorable | Neutral | Unfavorable | Total |
|---|---|---|---|---|---|
| Group 1 (p = 0.2336) | New Conventional V-shaped | 25 (5) | 30 (6) | 45 (9) | 100 (20)* |
| | | 33 (7) | 43 (9) | 24 (5) | 100 (21) |
| Group 2 (p = 0.5668) | New Conventional Flat-headed | 42 (8) | 21 (4) | 37 (7) | 100 (19) |
| | | 21 (4) | 47 (9) | 32 (6) | 100 (19) |

*One questionnaire was not available for the analysis.

tribution between the new and conventional toothbrushes were not significant in each group (p = 0.23 and 0.57).

## Discussion

This clinical trial attempted to evaluate the plaque removal efficacy of a new V-shaped toothbrush design with modified bristle arrangements. The toothbrush was developed to improve plaque removal efficacy on interproximal surfaces. The new Do Clear W toothbrush was compared to a conventional V-shaped toothbrush and a flat-headed toothbrush in a cross-over design study with a measured and controlled single use. The findings demonstrated the superior average percentage plaque removal efficacy of the new Do Clear W toothbrush over both conventional toothbrushes.

In the comparisons between the new toothbrush and a conventional flat-headed toothbrush, significant differences were found in average percentage plaque removal efficacy, while no significant differences were observed in the mean post-brushing plaque score. The calculation for average percentage plaque removal efficacy is based on using both pre- and post-brushing plaque scores, which accounts for differences among the groups at the onset. Since the amount of plaque removed is the more important issue, it is felt that the index of average percentage plaque removal efficacy may provide more relevant information on the efficacy of a toothbrush than merely comparing the simple mean post-brushing plaque scores.

The questionnaires showed similar preferences for the three toothbrushes tested. The percent of "unfavorable" responses to the new toothbrush was greater than that for "favorable" when the subjects used the new toothbrush as the first toothbrush in the study. However, this tendency was the opposite in the alternate group which used the new toothbrush design second. The discrepancy in the preference outcomes to the new toothbrush between two groups is possibly due to the order of group assignment, and should serve as a caution for making judgements about actual subject preferences for new products. Overall, no significant statistical difference was found between the percent responses to the new and conventional toothbrushes, regardless of when the responses were given.

It was clearly recognized that the preference for a toothbrush is one of major determinants of motivation and continued oral hygiene. Since there was no significant difference in the subject preferences for any of the toothbrushes tested, and given that the new toothbrush showed higher plaque removal efficacy than the conventional toothbrushes, it may be likely that oral health can be improved if individuals can be convinced to use the new configuration over conventional forms.

The rectangular shape of the bristle setting and the leaning structure in the neighboring two bundles in the toothbrush head were major modifications incorporated into the new toothbrush design. The modifications in the arrangement design employed in the new toothbrush may contribute to the improvement of plaque removal efficacy, both at the proximal region and on broad tooth surfaces. The dynamic mechanism of new designs in bristle arrangement should be clarified using laboratory tests for interproximal access efficacy and deposit removal, to further support the clinical findings of the present study.[8,9]

***For further correspondence with the author(s) of this paper, contact Dr. T. Hanioka—Haniokat@dent.osaka-u.acejp.***

## References

1. Axelsson P, Lindhe J: Effect of controlled oral hygiene procedures on caries and periodontal disease in adults. Results after 6 years. *J Clin Periodontol* 8:239–248, 1981.
2. Yankell SL, Saxer UD: Toothbrushing and toothbrushing techniques. In: *Primary Preventive Dentistry*, 5th Ed., Harris NO, Garcia-Godoy F, Eds., Appleton & Lange, Norwalk, pp. 77–101, 1999.
3. Bergenholtz A, Gustafsson LB, Segerlund N, Hagberg C, Nygaard-Östby P: Role of brushing technique and toothbrush design in plaque removal. *Scand J Dent Res* 92:344–351, 1984.
4. Yankell SL, Shi X, Emling RC: Laboratory interproximal access efficacy comparisons of a rippled bristle toothbrush and a flat manual toothbrush. *J Clin Dent* 4:82–84, 1993.
5. Battista GW, Petrone DM: Laboratory evaluations of interproximal access of two differently bristled manual toothbrushes. *J Clin Dent* 4:85–87, 1993.
6. Suzuki K, Sueta T, Shi R, Toyoda M, Kinoshita S: The effect of different types of toothbrushes on oral hygiene. *J Dent Health* 20:223–230, 1971.
7. Hanioka T, Tanaka M, Kataoka K, Ojima M, Shizukuishi S: Clinical evaluation of plaque removal efficacy of three toothbrushes. *J Clin Dent* 6:113–116, 1995.
8. Stabbe KA, Tishk MN, Overman PR, Love JW: A comparison of plaque reaccumulation and patient acceptance using a conventional toothbrush and a newly designed toothbrush. *Clin Prev Dent* 10:10–14, 1988.
9. Volpe AR, Emling RC, Yankell SL: The toothbrush – A new dimension in design, engineering, and clinical evaluation. *J Clin Dent* 3: C29–C33, 1992.

V-shaped toothbrush in 21 subjects, and the flat-headed toothbrush in 20 subjects. One questionnaire was not available in the second group. Plaque scores for 41 subjects and questionnaires for 40 subjects were, therefore, available for analysis.

Table I compares pre- and post-brushing mean plaque scores between the new and conventional V-shaped toothbrushes. The pre-brushing mean plaque scores of the new and conventional V-shaped toothbrush were similar in whole mouth comparison and at interproximal sites, though the differences were not statistically significant (p = 0.6641 and 0.5875, respectively). Post-brushing mean scores were statistically significantly lower in the new toothbrush group than in the V-shaped toothbrush group in the whole mouth comparisons (p = 0.005) and at interproximal sites (p = 0.010).

**Table I**
Comparison of Mean Plaque Scores in mm of the New Toothbrush and the Conventional V-Shaped Toothbrush

| | Mean (Standard Deviation) | | | |
|---|---|---|---|---|
| | Whole Mouth | | Interproximal Site | |
| Toothbrush | Pre-Brushing | Post-Brushing | Pre-Brushing | Post-Brushing |
| New | 1.21 (0.50) | 0.43 (0.24) | 1.28 (0.51) | 0.50 (0.26) |
| Conventional V-shaped | 1.25 (0.63) | 0.58 (0.23) | 1.32 (0.58) | 0.65 (0.24) |
| p-value | 0.6641 | 0.0053 | 0.5875 | 0.0103 |

Table II shows mean plaque scores of pre- and post-brushing with the new and flat-headed toothbrushes. Differences in the pre-brushing mean plaque scores between the new and flat-headed toothbrushes were not significant in whole mouth comparisons (p = 0.44) and at interproximal sites (p = 0.51). Post-brushing mean plaque scores from the new toothbrush were numerically less than those of the flat-headed toothbrush in both whole mouth comparison and at interproximal sites, but the differences did not reach significant levels (p = 0.13 and 0.13, respectively).

**Table II**
Comparisons of Mean Plaque Scores in mm of the New Toothbrush and the Conventional Flat-Headed Toothbrush

| | Mean (Standard Deviation) | | | |
|---|---|---|---|---|
| | Whole Mouth | | Interproximal Site | |
| Toothbrush | Pre-Brushing | Post-Brushing | Pre-Brushing | Post-Brushing |
| New | 1.18 (0.59) | 0.36 (0.25) | 1.30 (0.57) | 0.45 (0.27) |
| Flat-headed | 1.11 (0.50) | 0.46 (0.29) | 1.23 (0.44) | 0.56 (0.32) |
| p-value | 0.4401 | 0.1325 | 0.5050 | 0.1253 |

### *Whole Mouth Assessments*

The amount of plaque removal efficacy, represented as the percentage removed, can be seen in Figure 5 for whole mouth assessments. Subjects in the first group removed an average of 63.1% of plaque using the new toothbrush. When the same subjects used the conventional V-shaped toothbrush, they removed an average of 50.6% of the plaque. The average percentage plaque removal efficacy of the new toothbrush was 12.5% higher than for the conventional V-shaped toothbrush, and the difference was statistically significant (p = 0.0018). In the second group, the

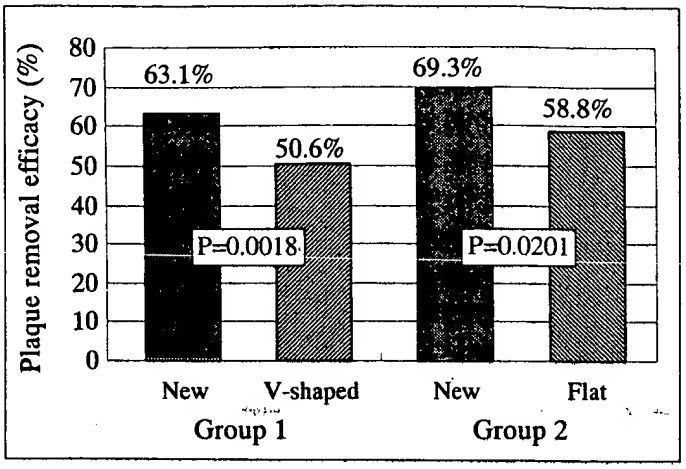


**Figure 5.** *Comparison of the plaque removal efficacy of toothbrushes in whole mouth average in each experimental group.*

subjects removed an average of 69.3% of the plaque when using the new toothbrush in the whole mouth assessment. The same subjects removed an average of 58.8% of plaque with the flat-headed toothbrush. The difference was 10.5% and statistically significant (p = 0.02).

### *Interproximal Assessments*

Figure 6 shows the average percentage plaque removal efficacy of the toothbrushes at the interproximal line angle. Similar to the whole mouth assessments, average plaque removal superiority of the new toothbrush was seen at the interproximal area. Nearly 10% difference was seen between the new toothbrush design and the standard V-shaped or flat-headed design on plaque removal, and the difference was statistically significant (p = 0.01 compared to the standard V-shape,and p = 0.03 compared to the flat-headed design).

### *Preference Questionnaire*

Table III summarizes the findings of the responses to the preference questionnaire. The subjects in each group chose similar responses to the preference items for both the new and conventional toothbrushes. Although the response percentages to the items varied from about 20% to 45%, the differences in the dis-

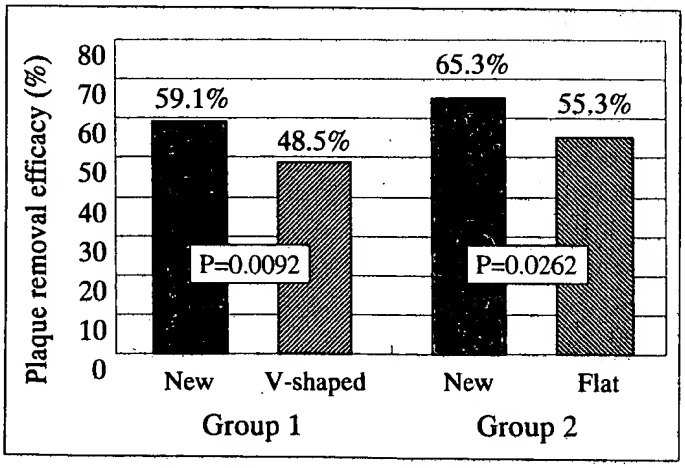


**Figure 6.** *Comparison of the plaque removal efficacy of toothbrushes at the proximal line angle in each experimental group.*